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| PPLICATION NO.  | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO |
|---|-----------------|----------------------|--------------------------|-----------------|
| 10/734,586  | 12/15/2003      | Richard Lewis Veech  | 604-703 1400<br>EXAMINER |                 |
| 23117   | 7590 03/24/2006 |                      |                          |                 |
| NIXON & VANDERHYE, PC                                   |                 |                      | JONES, DWAYNE C          |                 |
| 901 NORTH GLEBE ROAD, 11TH FLOOR<br>ARLINGTON, VA 22203 |                 | LOOK                 | ART UNIT                 | PAPER NUMBER    |
|   | •               |                      | 1614                     |                 |
|   |                 |                      | DATE MAILED: 03/24/2006  |                 |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)  |  |  |  |
|---|---|---|--|--|--|
| Office Action Communication   | 10/734,586  | VEECH, RICHARD LEWIS  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit  |  |  |  |
|   | Dwayne C. Jones   | 1614  |  |  |  |
| The MAILING DATE of this communication app Period for Reply   | ears on the cover sheet with the c  | orrespondence address   |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  | ATE OF THIS COMMUNICATION  16(a). In no event, however, may a reply be tim  rill apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE | l. ely filed the mailing date of this communication. O (35 U.S.C. § 133). |  |  |  |
| Status  |   |   |  |  |  |
| Responsive to communication(s) filed on      This action is FINAL. 2b)⊠ This      Since this application is in condition for allowant closed in accordance with the practice under E  | action is non-final.<br>ace except for formal matters, pro  |   |  |  |  |
| Disposition of Claims   |   |   |  |  |  |
| 4)  | election requirement.   | Examiner.   |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |   |  |  |  |
| ,—  |   |   |  |  |  |
| Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received. |   |   |  |  |  |
| Attachment(s)   |   |   |  |  |  |
| <ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br/>Paper No(s)/Mail Date</li> </ol>   | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa   |   |  |  |  |

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## **DETAILED ACTION**

## Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) compound claims 1-4, 17-18 and methods claim 5, 6, and 16 drawn to treating a cell that is subject to malfunction due to action of free radicals, toxic agents such as peptides and proteins and genetic defects deleterious to cell metabolism, insulin resistance, other glucose metabolism defects or defect inducing states, ischemia, head trauma, or increasing cell efficiency.

Group II, claim(s) 7 and 11-13, drawn to a method of accomplishing enteral or parenteral nutrition and providing a caloric substitute for carbohydrate.

Group III, claim(s) 8-10, drawn to a method of producing a physiologically acceptable ketosis.

Group IV, claim(s) 14 and 15, drawn to a method of increasing the efficiency of mitochondrial energy production in a human or animal not suffering from a chronic or acute metabolic disease.

2. The inventions listed as Groups I through IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. For instance, the special technical feature of the invention of Group I is directed to compositions and methods drawn to treating a cell that is subject to malfunction due to action of free radicals, toxic agents such as peptides and proteins and genetic defects deleterious to cell metabolism, insulin resistance, other glucose metabolism defects or defect inducing states, ischemia, head trauma, or increasing cell efficiency, which is not the expected outcomes for the inventions and special technical features of Groups II, III, and IV, which have outcomes in increasing the efficiency of mitochondrial energy production in a human or animal not suffering from a chronic or acute metabolic disease or parenteral nutrition.

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3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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In addition, should applicant should select the invention of Group I, Applicant is required to elect one species where the variable of n is clearly defined and to select one of the following methods to be treated for which examination will be restricted is additionally required. The species are as follows:

V a compound of formula (I) where the variable of n is defined and specified and;

VI treating a cell that is subject to malfunction due to action of free radicals;

VII treating a cell that is subject to malfunction due to action of toxic agents;

VIII treating a cell that is subject to malfunction due to action of insulin resistance;

IX treating a cell that is subject to malfunction due to action of other glucose metabolism defects or defect inducing states;

X treating a cell that is subject to malfunction due to action of ischemia;

XI treating a cell that is subject to malfunction due to action of head trauma;

XII treating a cell that is subject to malfunction due to action of increasing cell efficiency.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

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subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Claim 1 is directed to the compounds, and claims 5 and 16 lists various methods of treating a cell due to a variety of ailments and/or conditions

The following claim(s) are generic: claims 1, 5, and 16

- 5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The inventions listed as Groups I through IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. For instance, the special technical feature of the invention of Group I is directed to compositions and methods drawn to treating a cell that is subject to malfunction due to action of free radicals, toxic agents such as peptides and proteins and genetic defects deleterious to cell metabolism, insulin resistance, other glucose metabolism defects or defect inducing states, ischemia, head trauma, or increasing cell efficiency, which is not the expected outcomes for the inventions and special technical features of Groups II, III, and IV, which have outcomes in increasing the efficiency of mitochondrial energy production in a human or animal not suffering from a chronic or acute metabolic disease or parenteral nutrition.
- 6. A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made, see MPEP Sect. 812.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.

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Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the <u>cited U.S.</u> patents and patent application publications are available for download via the Office's PAIR, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. As an alternate source, <u>all U.S. patents and patent application</u> publications are available on the USPTO web site (<a href="http://www.uspto.gov">www.uspto.gov</a>), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).

PRIMARY EXAMINER

March 18, 2096